

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-0150003	Application No. 10/010,283
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant Carl-Axel Bauer et al.	
		Filing Date November 13, 2001	Group Art Unit 1617
(37 CFR §1.98(b))			

### U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1	5,684,199	11/04/1997	Francotte			

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	2	9703407-8	09/23/1998	Sweden				
	3	WO 92/11280	07/09/1992	WIPO				
	4	WO 98/15280	04/16/1998	WIPO				
	5	EP1085877	12/16/1999	Europe				
	6	WO 99/64014	12/16/1999	WIPO				
	7	EP0613371	03/06/2002	Europe				

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	8	Ankerst et al., "Tolerability of a High Dose of Budesonide/Formoterol in a Single Inhaler in Patients with Asthma," manuscript (24 pages), as submitted for publication to Pulm. Pharm. Ther. with letter dated February 6, 2003 to the EPO, later published as Vol. 16(3), pages 147-151 (2003).
	9	Ankerst et al., "Tolerability of a High Dose of Budesonide/Formoterol in a Single Inhaler in Patients with Asthma," Pulm. Pharm. Ther. Vol. 16(3):147-151 (2003) (abstract only).
	10	Bjerner et al., "Long-acting $\beta_2$ -agonists: how they are used in an optimal way?," Respiratory Medicine, Vol. 91, pages 587-591 (1997).
	11	Clinical Practice Guidelines, Expert Panel Report 2, Guidelines for the Diagnosis and Management of Asthma, NIH Publication No. 97-4051, July 1997.
	12	Haughney et al., "Adjustable maintenance treatment with budesonide/formoterol combination rapidly improves and maintains quality of life in asthma patients," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P379, submitted to EPO with letter dated February 6, 2003.
	13	Ind et al., "Managed Adjustable closing of budesonide/formoterol combination provides equivalent asthma control to fixed dosing at a lower overall dose," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P2450, submitted to EPO with letter dated February 6, 2003.
	14	Letter from AstraZeneca to EPO dated 6 February 2003 in EP Application 99930103.9.
	15	Lipworth, "A Single High Dose of Budesonide Rapidly Reverses Bronchoprotective Subsensitization and B2-Adrenoceptor Down-Regulation in Patients Receiving Regular Formoterol," J. Allergy Clin. Immunol., Page S152, Section 629, January 1998.

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	16	Lipworth, "Airway Subsensitvity with Long-Acting $\beta$ 2-Agonists," Drug Safety, Vol. 16(5), pages 295-308 (1997).
	17	Lipworth et al., "Effects of Treatment with Formoterol on Bronchoprotection against Methacholine," Amer. J. Med., Vol. 104, pages 431-438 (1998).
	18	Löfdahl C.G. et al., "Long-acting $\beta$ 2-adrenoceptor agonists: a new perspective in the treatment of asthma", The European Respiratory Journal, Vol. 4, pages 218-226 (1991).
	19	O'Byrne et al., "Additive Effects of Budesonide and Formoterol in Reducing Severe Asthma Exacerbations over 12 Months," abstract of presentation given at the June 1-5, 1997, Annual Meeting of Allergy and Clinical Immunology, published as abstract 266 in Allergy 52, Supp. 37-89 (1997).
	20	Olsson et al., "Adjustable maintenance treatment of asthma with budesonide and formoterol in a single inhaler," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P2451, submitted to EPO with letter dated February 6, 2003.
	21	Price et al., "Budesonide/formoterol with an adjustable maintenance plan costs less and is as effective as fixed dosing," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P2452, submitted to EPO with letter dated February 6, 2003.
	22	Rosenthal et al., "Efficacy, safety and cost of budesonide/formoterol in a single inhaler compared with budesonide plus formoterol as separate inhalers", European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P388, submitted to EPO with letter dated February 6, 2003.
	23	Scrip, The Dialog Corporation, 1562, page 21 (31 October 1990).
	24	Sung et al., "Randomized, Controlled Trial of Inhaled Budesonide as an Adjunct to Oral Prednisone in Acute Asthma," Academic Emergency Medicine, Vol. 5(3), pages 209-212 (1998).
	25	Decision of the EPO Opposition Division regarding patent EP-B-1210943, dated December 5, 2008.
	26	Statement of Grounds of Opposition to patent EP1085877 by Vectura Limited, received at the EPO on December 17, 2008.
	27	Statement of Grounds of Opposition to patent EP1085877 by Generics Limited, received at the EPO on December 19, 2008.
	28	Statement of Grounds of Opposition to patent EP1085877 by Norton Health Care Limited, received at the EPO on December 19, 2008
	29	Statement of Grounds of Opposition to patent EP1085877 by Ratiopharm GmbH, received at the EPO on December 17, 2008, translation attached.
	30	"What You Should Know About Symbicort Turbohaler?", AstraZeneca, May 2001, 4 pages.
	31	U.S. Examiner Rebecca Cook, USPTO Office Action in U.S. Serial No. 09/194,290, mailed August 16, 1999 (Rescinded) (5 pages)
	32	U.S. Examiner Rebecca Cook, USPTO Office Action in U.S. Serial No. 09/194,290, mailed March 27, 2000 (case abandoned October 2, 2000) (6 pages)
	33	U.S. Examiner Rebecca Cook, USPTO Office Action in U.S. Serial No. 09/670,457, mailed May 10, 2001 (case abandoned November 30, 2001) (6 pages)
	34	U.S. Examiner Jennifer M. Kim, USPTO Office Action in U.S. Serial No. 09/367,950, mailed December 18, 2000 (9 pages)

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	35	Fish & Richardson P.C., Amendment in Reply to Office Action dated December 18, 2001, in U.S. Serial No. 09/367,950, filed April 18, 2001 (8 pages)
	36	U.S. Examiner Jennifer M. Kim, USPTO Final Office Action in U.S. Serial No. 09/367,950, mailed May 21, 2001 (8 pages)
	37	Fish & Richardson P.C., Response to Final Office Action dated May 21, 2001, in U.S. Serial No. 09/367,950, filed August 21, 2001 (4 pages)
	38	U.S. Examiner Jennifer M. Kim, USPTO Office Action in U.S. Serial No. 09/367,950, mailed September 25, 2001 (8 pages)
	39	Fish & Richardson P.C., Response to Office Action dated May 21, 2001, in U.S. Serial No. 09/367,950, filed December 26, 2001 (3 pages)
	40	U.S. Examiner Jennifer M. Kim, USPTO Final Office Action in U.S. Serial No. 09/367,950, mailed April 15, 2002 (6 pages)
	41	U.S. Examiner Jennifer M. Kim, in U.S. Serial No. 09/369,950, Interview Summary dated September 17, 2002 (1 page)
	42	Fish & Richardson P.C., Notice of Appeal in U.S. Serial No. 09/367,950, filed October 9, 2002 (1 page)
	43	Fish & Richardson P.C., Request for Continued Examination and Amendment in Reply in U.S. Serial No. 09/367,950, filed December 10, 2002 (55 pages)
	44	U.S. Examiner Jennifer M. Kim, USPTO Office Action in U.S. Serial No. 09/367,950, mailed March 21, 2003 (9 pages)
	45	Fish & Richardson P.C., Response to Office Action dated March 21, 2003, in U.S. Serial No. 09/367,950, filed June 19, 2003 (9 pages)
	46	Fish & Richardson P.C., Supplemental Amendment filed July 3, 2003, in U.S. Serial No. 09/367,950 (8 pages)
	47	U.S. Examiner Jennifer M. Kim, Notice of Allowance mailed July 9, 2003, in U.S. Serial No. 09/367,950 (9 pages)
	48	U.S. Examiner Jennifer M. Kim, USPTO Office Action in U.S. Serial No. 09/367,950, mailed May 4, 2004 (12 pages)
	49	Fish & Richardson P.C., Reply to Office Action dated May 4, 2004, in U.S. Serial No. 09/367,950 filed November 1, 2004 (6 pages)
	50	U.S. Examiner Jennifer M. Kim, USPTO Office Action in U.S. Serial No. 09/367,950, mailed March 30, 2005 (14 pages)
	51	Fish & Richardson P.C., Amendment in Reply to Office Action dated March 30, 2005, in U.S. Serial No. 09/367,950, filed June 29, 2005 (17 pages)
	52	U.S. Examiner Jennifer M. Kim, USPTO Office Action in U.S. Serial No. 09/367,950, mailed September 21, 2005 (15 pages)
	53	Fish & Richardson P.C., Amendment in Reply to Office Action dated September 21, 2005, in U.S. Serial No. 09/367,950, filed November 15, 2005 (12 pages)
	54	U.S. Examiner Jennifer M. Kim, Advisory Action in U.S. Serial No. 09/367,950, mailed December 14, 2005 (3 pages)
	55	Fish & Richardson P.C., Brief on Appeal filed March 3, 2006, in U.S. Serial No. 09/367,950, filed March 3, 2006 (61 pages)

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	56	U.S. Examiner Jennifer M. Kim, Examiner's Answer in U.S. Serial No. 09/367,950, mailed June 16, 2006 (15 pages)
	57	Fish & Richardson P.C., Reply Brief on Appeal filed August 14, 2006, in U.S. Serial No. 09/367,950 (15 pages)
	58	U.S. Examiner Jennifer M. Kim, Communication regarding Appeal Brief in U.S. Serial No. 09/367,950, mailed September 12, 2006 (2 pages)
	59	U.S. Examiner Jennifer M. Kim, Notice of Non-Compliant Appeal Brief in U.S. Serial No. 09/367,950, mailed October 30, 2006 (4 pages)
	60	Fish & Richardson P.C., Amendment in Reply to Non-Compliant Appeal Brief dated October 30, 2006, in U.S. Serial No. 09/367,950 filed November 28, 2006 (8 pages)
	61	U.S. Examiner Jennifer M. Kim, Office Communication dated January 24, 2007, in U.S. Serial No. 09/367,950 (2 pages)
	62	Board of Appeals and Interferences, Order remanding to the Examiner, in U.S. Serial No. 09/367,950, dated August 28, 2007 (11 pages)
	63	U.S. Examiner Jennifer M. Kim, Interview Summary mailed October 22, 2007, in U.S. Serial No. 09/367,950 (4 pages)
	64	Fish & Richardson P.C., Interview Summary Following Board Decision of August 28, 2007, dated November 9, 2007 and re-filed November 21, 2007 in U.S. Serial No. 09/367,950 (13 pages)
	65	U.S. Examiner Jennifer M. Kim, Office Action in U.S. Serial No. 09/367,950, mailed December 4, 2007 (16 pages)
	66	Fish & Richardson P.C., Amendment in Reply to Office Action dated December 4, 2007, in U.S. Serial No. 09/367,950 filed June 3, 2008 (37 pages)
	67	U.S. Examiner Jennifer M. Kim, Final Office Action in U.S. Serial No. 09/367,950, mailed October 6, 2008 (21 pages)
	68	Fish & Richardson P.C., Amendment in Reply to Final Office Action dated October 6, 2008, in U.S. Serial No. 09/367,950 filed April 3, 2009 (20 pages)
	69	U.S. Examiner Kendra D. Carter, Office Action in U.S. Serial No. 10/665,240, mailed January 30, 2007 (18 pages)
	70	Fish & Richardson P.C., Amendment in Reply to Final Office Action dated January 30, 2007, in U.S. Serial No. 10/665,240, filed July 27, 2007 (30 pages)
	71	U.S. Examiner Kendra D. Carter, Final Office Action in U.S. Serial No. 10/665,240, mailed October 18, 2007 (25 pages)
	72	Fish & Richardson P.C., Amendment in Reply to Final Office Action dated October 18, 2007 in U.S. Serial No. 10/665,240, filed April 17, 2008 (14 pages)
	73	U.S. Examiner Kendra D. Carter, Advisory Action Before the Filing of an Appeal Brief in U.S. Serial No. 10/665,240, dated May 5, 2008 (5 pages)
	74	U.S. Examiner Kendra D. Carter, Final Office Action in U.S. Serial No. 10/665,240, mailed September 19, 2008 (16 pages)
	75	Fish & Richardson P.C., Amendment in Reply to Final Office Action dated September 19, 2008, in U.S. Serial No. 10/665,240, filed March 18, 2009 (21 pages)

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